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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,292	04/02/1999	DONNA G. ALBERTSON	023070-09140	3543
22434	7590	02/09/2007	EXAMINER	
BEYER WEAVER LLP P.O. BOX 70250 OAKLAND, CA 94612-0250			HARRIS, ALANA M	
		ART UNIT		PAPER NUMBER
				1643
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/285,292	ALBERTSON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Alana M. Harris, Ph.D.	1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 November 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 and 14-17 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 and 14-17 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Arguments and Amendments***

1. Claims 1-12 and 14-17 are pending.

Claim 1 has been amended.

Claims 1-12 and 14-17 are examined on the merits.

2. The Examiner acknowledges Applicants' representative's request for an interview, see page 8 of Remarks submitted November 20, 2006. Applicants' representative, Mr. Hunter is invited to call the Examiner and formally set up and interview.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Maintained Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

4. The rejection of claims 1-12 and 14-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Applicants reiterate the criteria for meeting the written description requirement, supply Google results describing the CYP24 gene and assert the said gene and consequently the claimed method were adequately described, see page 5 of Remarks. These points of

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view, provided documents and arguments have been carefully reviewed and considered, but found unpersuasive.

While the Examiner notes the Google search of *CYP24* gene provides enumerable "hits" and the gene is well established in the art, the crux of the issue is not that the gene is not well characterized and not established in the art, but how Applicants have defined the *CYP24* gene in their specification. Information provided in the specification sets forth "*CYP24* gene" is a DNA sequence that encodes a 24-hydroxylase enzyme...The term gene can refer to a mutated copy of the gene, or a fragment of the gene", see page 7, lines 10-12. It follows that the acronym *CYP24* encompasses a genus of molecules, such as nucleic acids, proteins and mRNA that are not necessarily wild type forms of *CYP24*. The term reads on a plethora of variant, mutated and alternate forms of *CYP24*. Applicants have not described *CYP24* with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the claimed invention. For the reasons of record and reiterated herein the rejection is maintained.

5. The rejection of claims 1-12 and 14-17 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting *CYP24* mRNA in human breast tumor *in vitro* specimens treated with 1,25-dihydroxyvitamin D-3 comprising RT-PCR, does not reasonably provide enablement for a method of detecting a predisposition to any cancer comprising detecting the level of *CYP24* nucleic acid or

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CYP24 protein in a biological sample and comparing said level with the level from a control sample is maintained.

Applicants assert “[t]he specification teaches a number of methods of detecting the CYP24 gene or protein product”, see page 7 of the Remarks, 4<sup>th</sup> paragraph.

Applicants also note several peer-reviewed papers in support of their claimed invention.

Applicants' arguments have been carefully reviewed, but found unpersuasive.

The Examiner does not doubt the ability of one of ordinary skill in the art to detect CYP24 mRNA and protein levels. Applicants are reminded the claims read on prevention and forecasting whether or not a person will develop cancer. This type of analysis is art known not to be an “exact science”. Moreover, the examples presented in the specification particularly note established breast cancer cell lines (MCF-7 and BT474). Clearly, it is known to those of ordinary skill in the art these cell lines are already deemed cancerous. Consequently, it is not clear how one of ordinary skill in the art would prevent breast cancer in a cell, and prevent the said cancer in a cell that has already been characterized. Hence, the specification is not commensurate with the scope of the claims. There is insufficient guidance in the specification providing methodology consistent with the claims. For the reasons of record and the reasons reiterated herein the rejection is maintained.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**ALANA M. HARRIS, PH.D.**

**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.

22 January 2007